ACTIVE Surveillance to improve the VALUE of Pharmacovigilance as a Public Health tool

Group III:
Evaluation of
Signals

Process Elements

- Operational definition of signal
- Screening algorithms
- Criteria for further evaluation post-screening
  - Confirmed/refuted
- Communication to public
  - Signal is being evaluated
  - Outcome of evaluation
- Common process across therapeutic areas & medicines

Multi-sector Advisory Board

- Committee charged with following
  - Prioritizing signals for evaluation
    - Designated events
    - Context essential (pre-clinical, clinical development, compelling clinical narrative/history)
  - Learn from past experience and “failures” to refine definitions and improve process
  - Provide guidance on elements to consider in signal interpretation and communication

FDA

- Epidemiologist involved in review of every NDA (integral part of review team) for early development of post-approval activities
  - Common training and guidance for consistency and transparency
  - Avoid ‘bad’ last minute decisions for post-approval activities
- Epidemiologist on Advisory Committees

Workforce and Training Needs

- Immediate and long-term needs
  - Drug safety workforce study required
  - Conducted rapidly
- Consensus we need more epidemiologists - funding of pharmacoepidemiology training programs
  - NIH
  - Industry
  - Private foundations
- Evaluate EIS model for pharmacoepidemiology training
- Create training opportunities to learn about epidemiology among drug safety workforce

Data Integration

- Multidisciplinary committee charged with design of an integrated, federated network of data for public health surveillance and research
  - Has a single point of contact, coordinating center
  - Preserves and uses local knowledge
  - Pilots a process for bringing together data from major government stakeholders (DOD, VA, CMS)
  - Improves real-time data access/reduces time lag
  - Establishes a process for accessing data:
    - How and who
    - Rapidly
  - Enables access to medical records for validation & links to vital statistics
  - Establishes common nomenclature, data definitions, algorithms
  - Considers implications of surveillance and program evaluation versus research and impact on communication

Methods

- Symposium to compare and contrast of methods and publicize the output
  - Explore application of other methods used in public health surveillance
- Publication of methods being used (e.g. MaxSPRT)
- AHRQ to fund studies of data mining methods performance (e.g. compare all methods on case examples for timing and consistency)
- AHRQ/FDA fund studies to develop, validate, and publicize algorithms for identify key safety outcomes in databases (e.g. liver failure)